IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

DAVID CHAVEZ, *individually and on behalf of all others similarly situated*, Plaintiff, v. CHURCH & DWIGHT CO. INC., Defendant.	Case No. 1:17-cv-01948 Hon. John J. Tharp, Jr. JURY TRIAL DEMANDED

PLAINTFF DAVID CHAVEZ'S RESPONSE TO DEFENDANT
CHURCH & DWIGHT'S NOTICE OF SUPPLEMENTAL AUTHORITY

Defendant provides *Ochoa v. Church & Dwight Co.*, Case No. 5:17-cv-02019 (C.D. Cal.) as supplemental authority (Dkt. 40). *Ochoa* is distinguishable.

A. The Dismissal Without Prejudice In *Ochoa* Does Not Support Dismissal Here

The *Ochoa* court dismissed mislabeling claims involving folic acid because plaintiff (1) failed to conduct the 12-sample test referred to in 21 C.F.R. §101.9(g); and (2) did not allege that the folic acid overage exceeded a reasonable excess consistent with good manufacturing practices. Neither of these grounds provides a basis for dismissing Plaintiff's claims.

First, courts in this District have held that the performance of a 12-sample test is not required at the pleading stage. *See Muir v. Nbty, Inc.*, 2016 U.S. Dist. LEXIS 129494, *22 (N.D. Ill. 2016); *Gubala v. CVS Pharmacy, Inc.*, 2016 U.S. Dist. LEXIS 32759, *27-29 (N.D. Ill. 2016).

Second, *Ochoa* is factually distinguishable. In *Ochoa*, the product's label stated that the product had 800 mcg of folic acid, which is only slightly below the Upper Tolerable Intake Limit. By contrast, the Amended Complaint alleges that the label of Defendant's product – Vitafusion – lists only 400 mcg of folic acid, when, in reality, it had ***three times*** that amount (1232 mcg).

Third, Plaintiff alleges facts in the Amended Complaint showing: (1) the degree of the misrepresentation; (2) the overage exceeds the Upper Tolerable Intake Limit; and (3) and the dangers associated therewith. These facts all support the inference that the overage is not a reasonable excess.[1] (*See Complt.* ¶¶2, 10, 12, 13, 15, 30-31, 53.)

[1] Insofar as *Ochoa*'s holding would support dismissal in this case (even with the greater disparity between the labelled amount of folic acid and the actual amount identified by testing), then, respectfully, *Ochoa* was wrongly decided. But even *Ochoa* does not support Defendant's requested outcome of dismissal *with* prejudice. At most *Ochoa* identifies pleading issues which can be cured by Plaintiff if the Court accepts *Ochoa's* premise that it is necessary to do so.

B. Defendant's Stay Argument Fails

Defendant also urges this Court to grant its Motion because the *Ochoa* court stayed proceedings based on primary jurisdiction. The *Ochoa* court reached its decision based on comments to a regulation and federal court decisions in California. However, the regulation's comments and case law from this Circuit and District do not support a stay.

The comments concern whether the FDA should allow manufacturers' product labels to slightly ***understate*** the amount of an ingredient stated on the label. Food Labeling: Revision of the Nutrition and Supplement Facts Labels, 81 Fed. Reg. 33742, 33964–65 (May 27, 2016). Nothing in the comments suggests that the FDA contemplates providing additional guidance on whether manufacturers may grossly ***overstate*** the amount of the vitamin content on a label. To the contrary, the FDA already suggested that it would not provide additional guidance on what constitutes a "reasonable excess" in its Final Rule. *See Final Rule*, 58 Fed. Reg. 2079, 2161, attached as Exhibit C to Plaintiff's Response Brief (Dkt. 27). Nor is there any reason to believe that the FDA will issue guidance that permits a manufacturer's products to contain a potentially dangerous amount of a vitamin (as is the case here) such that it can exceed the Upper Tolerable Intake Limit recognized by the National Institutes of Health. Thus, the FDA has not suggested that it will issue guidance on the specific issues presented here.

Further, unlike the authority relied upon by the Central District of California in *Ochoa*, this Circuit imposes a more rigorous standard before it will stay a case under the primary jurisdiction doctrine. *See Ryan v. Chemlawn Corp.*, 935 F.2d 129, 131 (7th Cir. 1991) (primary jurisdiction dismissal reversed because, among other things, the plaintiff sought money damages, the case involved independent state law claims, and no specialized knowledge was required beyond that needed for other cases); *Biffar v. Pinnacle Foods Grp.*, LLC, 2016 U.S. Dist. LEXIS 173595, *4

(S.D. Ill. 2016) (no stay because issue in consumer fraud case was whether consumers were deceived not about how FDA defined a term). When the additional guidance from the agency on the relevant issue is not forthcoming or concrete, courts do not issue stays. *See, e.g., Burton v. Hodgson Mill, Inc.*, 2017 U.S. Dist. LEXIS 53160, at *20-21 (S.D. Ill. 2017) (no stay despite argument that the "FDA may be in the process of formulating a more concrete definition of the term 'all natural'" where "DA last issued a call for proposals on the topic in the fall of 2016 and has not yet issued any further timeframe or next steps").

Notably, Defendant has not identified any specific adjudication that would address the "reasonable excess" issue and does not contend that it requested clarification from the FDA. These failures doom Defendant's stay request. In *NRDC v. Metro. Water Reclamation Dist. of Greater Chi.*, 175 F. Supp. 3d 1041 (N.D. Ill. 2016), this Court, citing *Ryan*, denied a stay for primary jurisdiction. In that case, the defendant pointed to "ongoing efforts by the federal and state EPAs and the IPCB to develop water quality standards that impose numeric limitations on phosphorus discharges" but "[did] not identify *any* proceedings, whether ongoing or that could be initiated, which would adjudicate" the specific issue of whether certain water quality standards were incorporated into permits and whether the defendant violated those standards. *Id*. at 1048. This Court denied the stay because, among other things, "absent some plausible proposal for obtaining a ruling on the question at hand, the Court has no confidence that its stay would be anything but a *de facto* dismissal of the plaintiff's claims without adjudication." *Id*. This Court also noted that "[i]f the [defendant] were earnest about deferring to an administrative ruling, presumably it would have explained what administrative proceedings could be initiated at this time." *Id*. *See also Dochak v. Polskie Linie Lotnicze Lot S.A.*, 189 F. Supp. 3d 798, 805-06 (N.D. Ill. 2016) (similar). The Court should rule similarly here.

Dated: February 5, 2018

Respectfully submitted,

DAVID CHAVEZ

/s/ Daniel R. Johnson

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CERTIFICATE OF SERVICE

Daniel R. Johnson, an attorney, hereby certifies that he caused a copy of the foregoing to be served on all counsel of record by electronically filing the document with the Clerk of Court using the ECF system this 5th day of February, 2018.

/s/ Daniel R. Johnson